

REMARKS/ARGUMENTS

By this Amendment, Claims 1, 10, 12 and 17 have been amended and the Specification has been amended. Thus, Claims 1-18 are pending.

Applicants have amended the Specification errors such as the stopper reference number 510 needed to be corrected on page 13, as well as some grammatical corrections on page 14.

The Examiner has asserted that the oath or declaration is defective. In particular, she asserts that the mailing address of each inventor is not identified in the oath or declaration but that such information may be provided on an application data sheet. To that end, Applicants have enclosed a copy (as Exhibit A) of the application data sheet, as filed, which provides the mailing address of each inventor. As such, Applicants respectfully request that the defective declaration assertion be withdrawn.

The Examiner has rejected Claims 1, 12 and 17, as well as dependent Claims 2-11, 13-16 and 18, under 35 U.S.C. §112, second paragraph as being indefinite. In particular, the Examiner has identified the phrases “the withdrawn position” (Claim 1), “the driver sensor” (Claim 12) and “the needle shielded position” (Claim 17) as lacking antecedent basis. To that end, Applicants have accordingly amended those claims to overcome this rejection and Applicants respectfully request that the §112, second paragraph be withdrawn.

The Examiner has rejected Claims 1-11, as well as Claims 12-18, under 35 U.S.C. §102(b) as already being taught by U.S. Patent No. 6,319,233 (Jansen).

Applicants respectfully disagree for the following reasons. In particular, the Examiner has identified various components of the Jansen injector as already teaching the structure of the present invention. However, whereas the present invention uses the sensor means (e.g., the cam

cone 342) to detect the end of the barrel 501 and thereby automatically trigger the shield placement, the Jansen injector requires user intervention to deploy its shield:

Following removal of the needle 18 from the patient, the user applies a greater force to the plunger rod than that applied during injection. Such force causes axial displacement of the end fitting, the spring and the shield with respect to the holder. The distance between the annular wall 66 of the end fitting (or the flange 24) and the second abutment surface 44 is sufficient to allow the shield stop member 58 to move far enough axially to where its retention by the holder stop member 48 is overcome by the force of the spring. In the preferred embodiment, this is accomplished as the inclined surfaces of the stop members slide past each other. The holder stop member 48 is also displaced radially as such sliding occurs due to the flexibility of the holder body portion which adjoins it. (emphasis added, Jansen, col. 6, lines 39-53).

This includes Jansen's second embodiment (Figs. 14-19):

In operation, the device 100 is employed in substantially the same manner as a conventional syringe, starting with the arrangement of elements shown in FIG. 16. The user pushes the plunger rod using his thumb while the flanges of the holder are engaged by the index and middle fingers of the same hand. Once the piston has been moved to an abutting position with the end of the syringe barrel, further pressure exerted by the user on the plunger rod causes axial movement of the syringe itself. Due to the abutting relation of the coils of the spring to each other, the spring in effect forms a solid connection between the syringe flange and the proximal end of the shield. Axial movement of the syringe accordingly causes corresponding axial movement of the shield until the collar 114 moves beyond the stop member 116, as shown in FIG. 18. Expansion of the spring causes the shield to move to an extended position, as shown in FIG. 17. (emphasis added, Jansen, col. 7, line 66 to col. 8, line 14).

To that end, Applicants have amended Claim 1 to specify "...and to automatically trigger activation of the shield driver means upon detection" since no user intervention is required to deploy the shield, and thereby distinguish over Jansen. Claim 12 has also been amended to specify "to automatically cover the needle after said driver detects the end of the barrel" and thereby also distinguish over Jansen.

Applicants submit that the Examiner's explanation about what deploys the Jansen shield 28 at the bottom of page 6 of the Office Action ("Fig. 5 discloses that once the stopper hits the end of the barrel and is sensed by the contact between the arm and 24, then the spring is released as shown in Fig. 4") is incorrect. There is no detection of the end of the barrel in Jansen. Rather,

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it is the user's increased force applied to the plunger that deploys the shield 28. The Jansen mechanism that does this is clearly shown in Fig. 5. Once the user applies sufficient force to the plunger, the element 32 engages the stop member 58 to apply enough force to slide around the stop member 48 which releases the spring 30 and deploys the shield 28 (see Jansen, col. 6, lines 40-65). Fig. 3 depicts this mechanism is nowhere near the end of the barrel but is rather closer to the proximal end of the Jansen device. Thus, there is no "end of the barrel" detection in Jansen as specified in Claims 1 or 12.

The Examiner identified some concern about the "sensor means" in the present invention:

...Please note that Applicant has not claimed at what points the sensor moves with the driver or for what duration/length) and in slidable contact with an exterior surface of said cartridge barrel or an interior surface of said housing (Fig. 5 discloses that portions 66 and 32 [reference numbers correspond to Jansen] are in slidable contact with both the exterior surface of the cartridge barrel and the interior surface of the housing (64)), the sensor means arranged to detect an end profile of the barrel or housing and to trigger activation of the shield driver means upon detection (the sensor means (66 and 32) detect an end profile of the barrel through the stopper's detection of the end of the barrel as seen in Fig. 4, and this triggers the sensor means to activate the shield driver means (30) upon detection. Please note that Applicant's claim language is very broad as to how the sensor means detects the end profile of the barrel or housing, and is broad enough to include the examiner's interpretation). Office Action, page 4.

To overcome that concern, Applicants have amended Claim 1 to specify that the sensor means is part of the driver rather than being "movable with said driver".

Thus, for all of the above reasons, Applicants respectfully submit that Claims 1 and 12, as amended, are patentable over Jansen and Applicants respectfully request that the §102(b) rejection be withdrawn.

Claim 2 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 3 is dependent upon Claim 2 and is patentable for the same reasons.

Claim 4 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 5 is dependent upon Claim 4 and is patentable for the same reasons.

Claim 6 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 7 is dependent upon Claim 6 and is patentable for the same reasons.

Claim 8 is dependent upon Claim 1 and is patentable for the same reasons. Furthermore, the Examiner fails to identify the structure in Fig. 5 that discloses a sensor means comprising one or more deformable arms attached or integrally formed with the driver. Thus, for all of these reasons, Claim 8 is patentable over Jansen.

Claim 9 is dependent upon Claim 8 and is patentable for the same reasons. Again, the Examiner fails to identify what in Figs. 3-5 discloses one or more deformable arms that is biased against the exterior surface of the cartridge barrel in Jansen and is arranged to follow the surface profile of the barrel, as specified in Claim 9. Thus, for all of these reasons, Claim 9 is patentable over Jansen.

Claim 10 is dependent upon Claim 8 and is patentable for the same reasons. Again, the Examiner fails to identify what in Figs. 3-5 discloses a release mechanism having a catch provided on a radial outer surface of each deformable arm, as specified in Claim 10. Thus, for all of these reasons, Claim 10 is patentable over Jansen. It should be noted that Claim 10 was amended to correct a grammatical error in the word “radial”.

Claim 11 is dependent upon Claim 1 and is patentable for the same reasons. Again, the Examiner fails to identify what in Figs. 3 and 5 discloses a driver and sensor means which are as single molded plastic element, as specified in Claim 10. In particular, the Examiner previously identified part 30 (spring) of Jansen as the analog to the shield driver means of the present

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invention and the analog to the sensor means as the element 32/66. However, the spring 30 and element 32/66 are shown and discussed in Jansen as separate elements. Thus, for all of these reasons, Claim 11 is patentable over Jansen.

Claim 13 is dependent upon Claim 12 and is patentable for the same reasons.

Claim 14 is dependent upon Claim 12 and is patentable for the same reasons. Furthermore, the Examiner asserts that the “two sensor elements” (specified in Claim 14) are the “two sides of the arm flange portion opposite 20” that detect the end of the barrel. It is unclear what is meant by this phrase. Is that the holder 26 or the shield 28, or the element 32/66? Moreover, there is no structure in Jansen that detects the end of the barrel as discussed previously. Thus, for all of these reasons, Claim 14 is patentable over Jansen.

Claim 15 is dependent upon Claim 12 and is patentable for the same reasons.

Claim 16 is dependent upon Claim 15 and is patentable for the same reasons.

Claim 17 is dependent upon Claim 15 and is patentable for the same reasons.

Claim 18 is dependent upon Claim 1 and is patentable for the same reasons.

Thus, Applicants respectfully submit that, as amended, Claims 1-18 are now in condition for allowance. Accordingly, prompt and favorable examination on the merits is respectfully requested.

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Should the Examiner believe that anything further is desirable in order to place the application in even better condition for initial examination and allowance, the Examiner is invited to contact Applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
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July 24, 2007

Please charge or credit our
Account No. 03-0075 as necessary
to effect entry and/or ensure
consideration of this submission.

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EXHIBIT “A”

(Copy of Application Data Sheet filed January 27, 2007)

APPLICATION DATA SHEET

Electronic Version v14

Stylesheet Version v14.0

Title of Invention	SYRINGE WITH AUTOMATICALLY TRIGGERED SAFETY SLEEVE	
Application Type:	regular, utility	
Attorney Docket Number:	S2082/20003	
Correspondence address:		
Customer Number:	03000	*03000*
Continuing Data:		
This is a National Stage of IB application number PCT/IB2004/051319, filed 2004-07-28 , now pending.		
Priority Data:		
Doc.No: 60/491,196; Country - US; Date: 2003-07-31 us-priority-claimed		
Doc.No: 60/519,724; Country - US; Date: 2003-11-14 us-priority-claimed		
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as our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

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